



A lateral flow device to detect emtricitabine in urine for PrEP and ART adherence monitoring.

Thomas H. Vanderford, Ph.D.

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- **Disclosure:** CDC authors are named in US. Government patents (US20210253738) and patent applications on the monoclonal antibody for the detection of the antiretroviral drug emtricitabine.
 - **Disclaimer:** The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention (CDC).



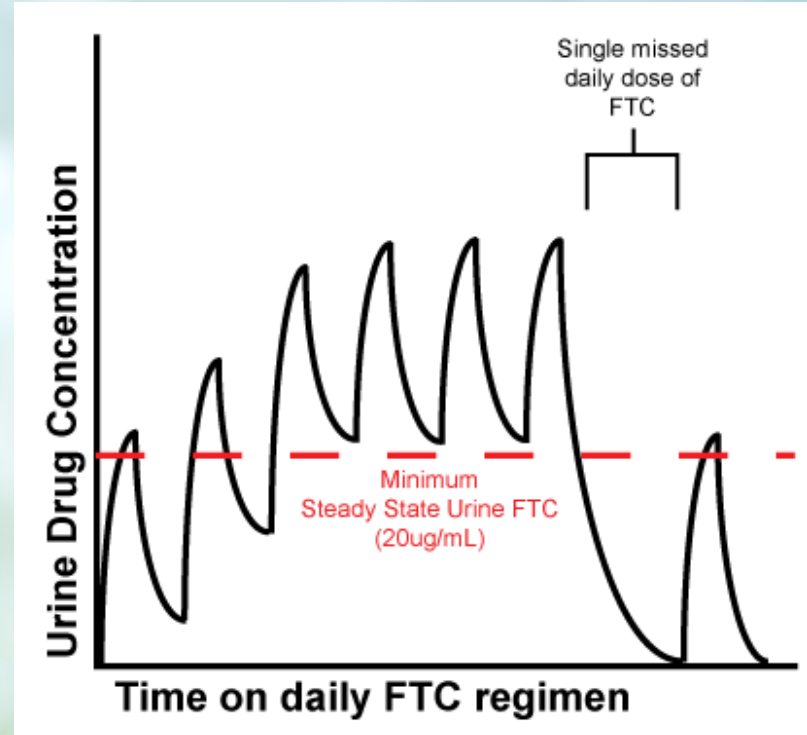
Solutions for antiretroviral drug adherence monitoring

- Adherence to daily antiretroviral regimens is critical for viral load suppression and the efficacy of PrEP
- Inexpensive, rapid tests for antiretrovirals will allow real-time counseling at the point-of-care
- Emtricitabine (FTC) has a fixed dose in PrEP and treatment regimens making it a good target for **daily** adherence monitoring



FTC as a daily adherence marker

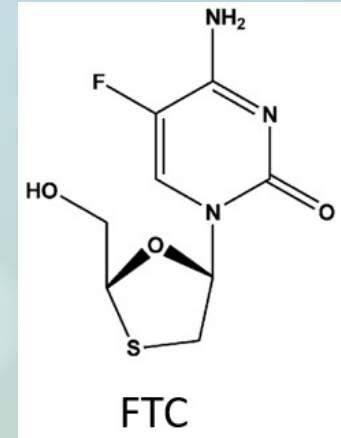
- FTC is excreted rapidly in urine
- We wanted to identify a marker of daily adherence in urine
- Prior work suggests ~20 $\mu\text{g/mL}$ is a suitable 24-hour threshold for urine FTC





Development of a lateral flow assay for FTC

- Lateral flow assays rely on antibody recognition of the assay target
- Generated mouse monoclonal antibodies against FTC
- Identified 5D2 as a highly FTC-specific antibody with no cross-reactivity to 3TC and any other nucleosides or nucleotides (Youngpairoj, AIDS, 2022)

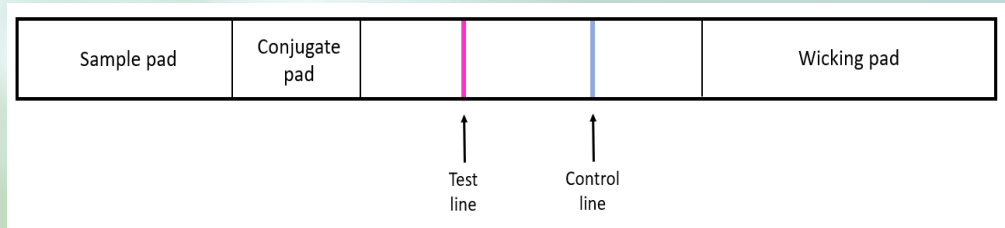




FTC lateral flow assay kit

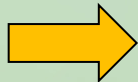
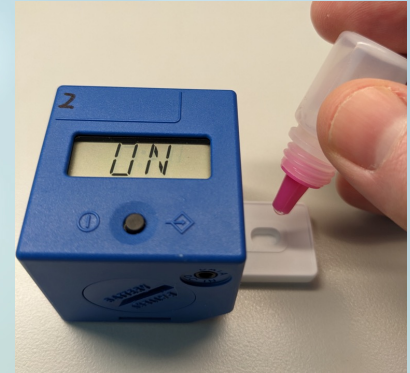
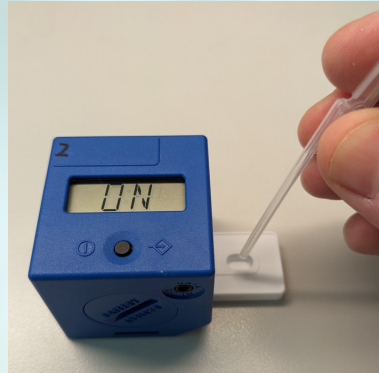


- Chembio CUBE Reader measures line intensities and interprets an FTC concentration
- The reader will return a **“Adherent”** or **“Non-adherent”** result based on this measurement





FTC LFA kit procedure



20 minute
assay
readout

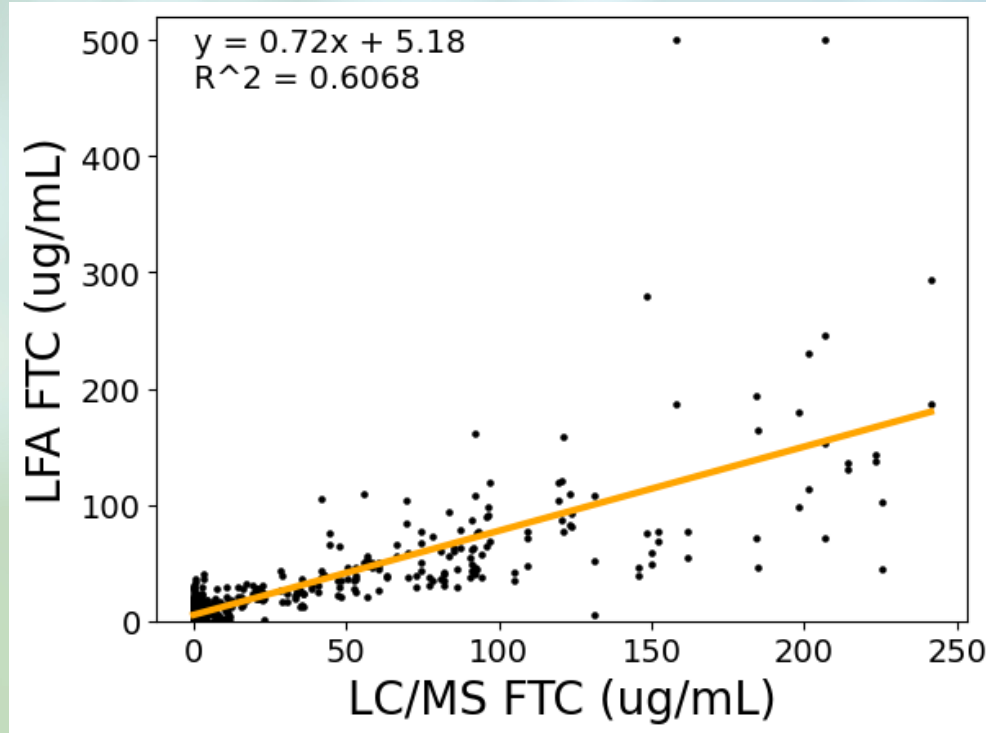


Experimental and clinical sample populations

- 3 study sample sets with known urine FTC concentrations as measured by gold-standard LC/MS:
 - 102 FTC-negative urine specimens
 - 191 longitudinal urine samples from 36 participants with observed single FTC dosing
 - 91 urine samples from people with HIV prescribed FTC-containing ART
 - Adherence determined by plasma FTC levels



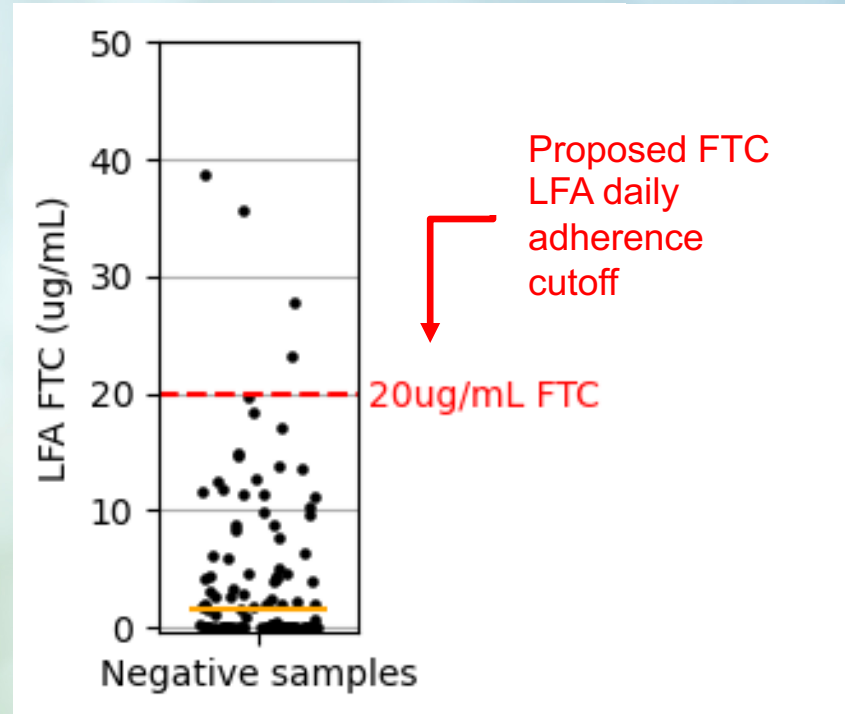
FTC LFA is highly concordant with LC/MS quantitated FTC





FTC negative samples fall below threshold

- 102 confirmed negative urine specimens were measured by FTC-LFA
- <4% of samples were over the proposed threshold for a daily adherence cutoff





FTC LFA has high performance on samples from ART treated persons

- Participant daily treatment adherence categorized by plasma FTC concentration using LC/MS:
 - 51 adherent
 - 40 non-adherent
- With a **20 $\mu\text{g/mL}$** LFA daily adherence cutoff:
 - 91.18% sensitivity
 - 96.20% specificity
 - 96.88% positive predictive value
 - 89.41% negative predictive value



Conclusions and next steps

- We developed an inexpensive and rapid FTC-specific urine lateral flow assay for adherence monitoring at point-of-care visits
- The assay has high sensitivity and specificity with a threshold for daily adherence
- The assay uses a common reader for objective result reporting
- We are interested in evaluating the clinical performance of this assay and its ability to improve adherence



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Matthew Reed

For more information
contact me:

smq9@cdc.gov

